DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

February 13, 2001

Ref: 2001-DAL-WL- 09

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Lenny M. Pippen
President
Schwan's Sales Enterprises Manufacturing, Inc.
115 West College Drive
Marshall, MN 56259

Dear Mr. Pippen:

We inspected your food manufacturing operation at 1251 Scarborough Lane, Pasadena, Texas, on November 28/29, December 18, 20/21, 2000, and January 19, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123. These deviations, some of which were previously brought to your firm's attention, cause your seafood containing products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

Our inspection revealed your processing of seafood containing products deviates from the regulations contained in 21 CFR Part 123 as follows:

- You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6 (b). However, your firm does not have a HACCP plan for shrimp egg rolls addressing the hazard of sulfites.

- You must maintain complete sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11 (c). However, your firm had no sanitation monitoring records or procedures in all eight areas of sanitation, including the health conditions of employees and the maintenance of hand-washing/toilet facilities.

Please note that the investigator advised you that your firm should address the potential hazard of Clostridium botulinum toxin formation for your Modified

Atmosphere Packaged (MAP) shrimp egg rolls. You may wish to submit private laboratory study information to FDA for evaluation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection your firm was issued a Form FDA-483 which is a list of the Investigators' observations of deviations noted during the inspection (attached). It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to seizure, and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your corrections. Your reply should be sent to Gwendolyn Sue Gilbreath, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

MAC:gsg

Attachment

cc: Mr. William M. Hirsch, Operations Manager
Schwan's Sales Enterprises Manufacturing, Inc.
1251 Scarborough Lane
Pasadena, Texas 77506